

AUG 11 2003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Victor J. Dzau, et al.

Docket No.: 39753-0021C3

Serial No.:

09/875,305

Group Art Unit: 1636

Filing Date:

June 5, 2001

Examiner: Marvich, Maria

For:

**THERAPEUTIC USE OF CIS-ELEMENT DECOYS IN VIVO**

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

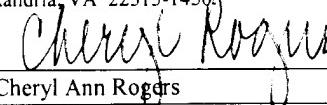
This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --  
 (2) It is being filed within 3 months of entry of a national stage  
-- OR --

**CERTIFICATE OF MAILING (37 CFR 1.10(a))**

CERTIFICATE OF MAILING BY "EXPRESS MAIL" - Rule 10: I hereby certify that this correspondence is being deposited on August 11, 2003 with the U.S. Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10 as Express Mail No. EV346725809US addressed to: Mail Stop: RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: August 11, 2003

  
Cheryl Ann Rogers

- (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --  
 (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- a certification as specified in §1.97(e) is provided below; **or**
- a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$180.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- Fee Authorization.* The Commissioner is authorized to charge any required fees, additional fees, or credit any overpayment to Deposit Account 08-1641 (Docket No. 39753-0021C3).

Respectfully submitted,

Dated: August 11, 2003

By:   
Ginger R. Dreger  
Reg. No. 33,055

**HELLER EHRMAN WHITE & MCAULIFFE LLP**

**Customer No. 25213**  
275 Middlefield Road  
Menlo Park, CA 94025-3506  
Telephone: (650) 324-7000  
Facsimile: (650) 324-0638

**SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT**

PTO-1449

ATTY. DOCKET NO.:

39753-0021C3

SERIAL NO.:

09/875,305

APPLICANT : Victor J. Dzau, et al.

FILING DATE: 6/5/01

GROUP: 1636

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE

**FOREIGN PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Abeyama, K., et al., "A Role for NF-kappaB-dependent Gene Transactivation in Sunburn", J. Clin. Invest 2000 Jun;105(12):1751-9.
	Bishop-Bailey, D., et al., "Endothelial Cell Apoptosis Induced by th Peroxisome Proliferator-activated Receptor (PPAR) Ligand 15-decoy-Delta 12, 14-prostaglandin J2", J. Biol. Chem. 1999 Jun 11;274(24):17042-8.
	Bonham, C.A., et al., "Marked Prolongation of Cardiac Allograft Survival by Dentritic Cells Genetically Engineered with NF-kappa B Oligodeoxynucleotide Decoys and Adenoviral Vectors Encoding CTLA4-Ig", J. Immunol 2002 Sep 15;169(6):3382-91.
	Borgatti, M., et al., "Cationic Liposomes as Delivery Systems for Double-stranded PNA-DNA Chimeras Exhibiting Decoy Activity Against NF-kappaB Transcription Factors", Biochem Pharmacol 2002 Aug 15;64(4):609-16.
	Breuer-McHam, J., et al., "Activation of HIV in Human Skin by Ultraviolet B Radiation and its Inhibition by NFkappaB Blocking Agents", Photochem Photobiol 2001 Dec;74(6):805-10.
	Cho-Chung, Y.S., et al., "Oligonucleotides as Transcription Factor Decoys", Curr. Opin. Mol. Ther. 1999 Jun;1(3):386-92.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>PTO-1449</b>		<b>ATTY. DOCKET NO.:</b> <b>39753-0021C3</b>	<b>SERIAL NO.:</b> <b>09/875,305</b>
		<b>APPLICANT :</b> Victor J. Dzau, et al.	
		<b>FILING DATE:</b> 6/5/01	<b>GROUP:</b> 1636
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	Cooper, J.A., Jr., et al., "Attenuation of Interleukin-8 Production by Inhibiting Nuclear Factor-kappaB Translocation Using Decoy Oligonucleotides", Biochem. Pharmacol. 2000 Mar 15;59(6):605-13.		
	D'Acquisto, F., et al., "Local Administration of Transcription Factor Decoy Oligonucleotides to Nuclear Factor-kappaB Prevents Carrageein-induced Inflammation in Rat Hind Paw", Gene Ther. 2000 Oct; 7(20):1731-7.		
	D'Acquisto, F., et al., "Transcription Factor Decoy Oligodeoxynucleotides to Nuclear Factor-kappaB Inhibit Reverse Passive Arthus Reaction in Rat", Naunyn Schmiedebergs Arch. Pharmacol 2001 Nov;364(5):422-9.		
	Feeley, B.T., et al., "Nuclear Factor-kappaB Transcription Factor Decoy Treatment Inhibits Graft Coronary Artery Disease After Cardiac Transplantation in Rodents", Transplantation 2000 Dec 15;70(11):1560-8.		
	Franco, A.V., et al., "The Role of NF-kappa B in TNF-related Apoptosis-inducing Ligand (TRAIL)-induced Apoptosis on Melanoma Cells", J. Immuno. 2001 May 1;166(9):5337-45.		
	Giannoukakis, N., et al., "Prolongation of Cardiac Allograft Survival Using Dendritic Cells Treated with NF-kB Decoy Oligodeoxyribonucleotides", Mol. Ther. 2000 May;1(5):430-437 (part 1 of 2 parts).		
	Griesenback, U., et al., "Anti-inflammatory Gene Therapy Directed at the Airway Epithelium", Gene Ther. 2000 Feb;7(4):306-13.		
	Hess, D.C., et al., "Hypertonic Mannitol Loading of NF-kappaB Transcription Factor Decoys in Human Brain Microvascular Endothelial Cells Blocks Upregulation of ICAM-1", Stroke 2000 May;31(5):1179-86.		
	Kawauchi, M., et al., "Gene Therapy for Attenuating Cardiac Allograft Arteriopathy Using Ex-Vivo E2F Decoy Transfection by HVJ-AVE-liposome Method in Mice and Nonhuman Primates", Circ. Res. 2000 Nov 24;87(11):1063-8.		
	Khaled, A.R., et al., "Use of Phosphorothioate-modified Oligodeoxynucleotides to Inhibit NF-kappaB Expression and Lymphocyte Function", Clin. Immunol. Immunopathol. 1998 Feb; 86(2):170-9.		
	Kitamoto, S., et al., "Increased Activity of Nuclear Factor-kappaB Participates in Cardiovascular Remodeling Induced by Chronic Inhibition of Nitric Oxide Synthesis in Rats", Circulation 2000 Aug 15;102(7):806-12.		
	Kupatt, C., et al., "Retroinfusion of NfkappaB Decoy Oligonucleotide Extends Cardioprotection Achieved by CD18 Inhibition in a Preclinical Study of Myocardial Ischemia and Retroinfusion in Pigs", Gene Ther. 2002 Apr;9(8):518-26.		
	Kupatt, C., et al., "Tumor Necrosis Factor-alpha Contributes to Ischemia- and Reperfusion-induced Endothelial Activation in Isolated Hearts", Circ. Res. 1999 Mar 5;84(4):392-400.		
	Li, Y., et al., S100beta Induction of the Proinflammatory Cytokine Interleukin-6 in Neurons", J. Neurochem 2000 Jan;74(1):143-50.		
	Matsushita, H., et al., "Hypoxia-induced Endothelial Apoptosis Through Nuclear Factor-kappaB (NF-kappaB)-mediated bcl-2 Suppression: In Vivo Evidence of the Importance of NF-kappaB in Endothelial Cell Regulation", Circ. Res. 2000 May 12;86(9):974-81.		
	Morishita, R., et al., "In Vivo Transfection of CIS Element "decoy" Against Nuclear Factor-kappaB Binding Site Prevents Myocardial Infarction", Nat Med. 1997 Aug;3(8):894-9.		
EXAMINER	DATE CONSIDERED		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>PTO-1449</b>		<b>ATTY. DOCKET NO.:</b> <b>39753-0021C3</b>	<b>SERIAL NO.:</b> <b>09/875,305</b>
		<b>APPLICANT :</b> Victor J. Dzau, et al.	
		<b>FILING DATE:</b> 6/5/01	<b>GROUP:</b> 1636
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	Nakamura, H., et al., "Prevention and Regression of Atopic Dermatitis by Ointment Containing NF-kB Decoy Oligodeoxynucleotides in NC/Nga Atopic Mouse Model", Gene Ther. 2002 Sep;9(18):1221-9.		
	Nishio, E., et al., "The Potentiation of Ox-LDL Induced Apoptosis by Inhibition of NF-kappaB", Life Sci. 2000 Sep;67(16):1983-92.		
	Ono, S., et al., "Decoy Administration of NF-kappaB into the Subarachnoid Space for Cerebral Angiopathy", Hum. Gene Ther. 1998 May 1;9(7):1003-11.		
	Quan, N., et al., "Administration of NF-kappaB Decoy Inhibits Pancreatic Activation of NF-kappaB and Prevents Diabetogenesis by Alloxan in Mice", FASEB J. 2001 Jul;15(9):1616-8.		
	Romano, M.F., et al., "Enhancement of Cytosine Arabinoside-induced Apoptosis in Human Myeloblastic Leukemia Cells by NF-kappa B/Rel-specific Decoy Oligodeoxynucleotides", Gene Ther. 2000 Jul;7(14):1234-7.		
	Sakaue, G., et al., "NF-kappa B Decoy Suppresses Cytokine Expression and Thermal Hyperalgesia in a Rat Neuropathic Pain Model", Neuroreport 2001 Jul 20; 12(10):2079-84.		
	Sawa, Y., et al., "A Novel Strategy for Myocardial Protection Using in Vivo transfection of CIS Element 'Decoy' Against NfkappaB Binding Site: Evidence for a Role of NfkappaB in Ischemia-reperfusion Injury", Circulation 1997 Nov 4;96(9 Suppl):II-280-4; discussion II-285.		
	Sharma, H.W., et al., "The NF-kappaB Transcription Factor in Oncogenesis", Anticancer Res. 1996 Mar-Apr;16(2):589-96.		
	Shibuya T., et al., "A Double-strand Decoy DNA Oligomer for NF-kappaB Inhibits TNFalpha-induced ICAM-1 Expression in Sinusoidal Endothelial Cells", Biochem. Biophys. Res. Commun. 2002, Oct 18;298(1): 10-16.		
	Shintani T., et al., "Intraoperative Transfection of Vein Grafts with the NfkappaB Decoy in a Canine Aortocoronary Bypass Model: A Strategy to Attenuate Intimal Hyperplasia", Ann Thorac. Surg. 2002, Oct;74(4):1132-7, discussion 1137-8.		
	Sumitomo, M., et al., "An Essential Role for Nuclear Factor KappaB in Preventing TNF-alpha-induced Cell Death in Prostate Cancer Cells", J. Urol. 1999 Feb;161(2):674-9.		
	Suzuki, J., et al., "Decoy Against Nuclear Factor-kappa B Attenuates Myocardial Cell Infiltration and Arterial Neointimal Formation in Murine Cardiac Allografts", Gene Ther. 2000 Nov;7(21):1847-52.		
	Takeuchi T., et al., "Nuclear Factor-kappaB and TNF-alpha Mediate Gastric Ulceration Induced by Phorbol Myristate Acetate", Dig. Dis. Sci. 2002 Sep;47(9):2070-8.		
	Tomita, N., et al., "In Vivo Administration of a Nuclear Transcription Factor-kappaB Decoy Suppresses Experimental Crescentic Glomerulonephritis", J. AM. Soc. Nephrol 200 Jul;11(7):1244-52.		
	Tomita, N., et al., "Transcription Factor Decoy for NfkappaB Inhibits TNF-alpha-induced Cytokine and Adhesion Molecule Expression in Vivo", Gene Ther. 2000 Aug;7(15):1326-32.		
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>PTO-1449</b>		<b>ATTY. DOCKET NO.:</b> <b>39753-0021C3</b>	<b>SERIAL NO.:</b> <b>09/875,305</b>
<b>APPLICANT :</b> Victor J. Dzau, et al.			
		<b>FILING DATE:</b> 6/5/01	<b>GROUP:</b> 1636
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
Tomita, T., et al., "Transcription Factor Decoy for NFkappaB Inhibits Cytokine and Adhesion Molecule Expressions in Synovial Cells Derived From Rheumatoid Arthritis", <i>Rheumatology (Oxford)</i> , 2000 Jul;39(7):749-57.			
Tomita, N., et al., "Transcription Factor Decoy for Nuclear Factor-kappaB Inhibits Tumor Necrosis Factor-alpha-induced Expression of Interleukin-6 and Intracellular Adhesion Molecule-1 in Endothelial Cells", <i>J. Hypertens</i> 1998 Jul;16(7):993-1000.			
Ueno, T., et al., "Nuclear Factor-kappa B Decoy Attenuates Neuronal Damage After Global Brain Ischemia: A Future Strategy for Brain Protection During Circulatory Arrest", <i>J. Thorac Cardiovasc. Surg.</i> 2001 Oct;122(4):720-7.			
Vos, I.H., et al., "NfkappaB Decoy Oligodeoxynucleotides Reduce Monocyte Infiltration in Renal Allografts", <i>FASEB J.</i> 2000 Apr;14(5):815-22.			
Yokoseki, O., et al., "CIS Element Decoy Against Nuclear Factor-kappaB Attenuates Development of Experimental Autoimmune Myocarditis in Rats", <i>Circ. Res.</i> 2001 Nov 9;89(10):899-906.			
Yoshimura, S., et al., "Inhibition of Intimal Hyperplasia After Balloon Injury in Rat Carotid Artery Model Using CIS-element 'Decoy' of Nuclear Factor-kappaB Binding Site as a Novel Molecular Strategy", <i>Gene Ther.</i> 2001 Nov;8(21):1635-42.			
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

